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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,734	03/24/2004	Alberto Gimona	4-31588B / C1	5415

1095 7590 08/25/2004

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,734	GIMONA ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of preliminary amendment and remarks filed 03/24/04.

Priority

Examiner acknowledges applicants' claim for benefit of a prior nonprovisional application number 09/950,538 as a continuation of the co-pending application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2 and 4-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujimoto et al. (WO 99/11605).

Fujimoto teaches a method of treating cyclooxygenase-2 dependent disorders in mammals and the method comprises administering to a mammal in need thereof an effective amount of cyclooxygenase-2 inhibiting amount of 5-alkyl-2-arylaminophenylacetic acids or pharmaceutically acceptable salts (abstract and claims 1 and 6).

One of the 5-alkyl-2-arylaminophenylacetic acid is 5-methyl-2- (2'-chloro-6'-fluoroanilino) phenylacetic acid where R is methyl, R1 is fluoro, R2 is hydrogen, R3 is hydrogen and R5 is chloro (page 3, lines 16-19). Fujimoto further teaches administering a composition comprising an effective amount of 5-alkyl-2-arylaminophenylacetic acids and pharmaceutically acceptable carriers and excipients (claim 5). The pharmaceutically acceptable carriers are lactose, dextrose, mannitol, silica, stearic acid, magnesium aluminum silicate,

polyvinylpyrrolidone, starches, alginic acid and colorants and flavors (page 19, lines 3 and 11-18). The composition is formulated as enteral or parenteral dosages, in tablet or capsule form (page 19, lines 10 and 24). On page 20, last two lines , Fujimoto discloses that a dose contains 5 and 500 mg active ingredient.

Fujimoto teaches the method of treating cyclooxygenase-2 dependent disorder but is silent on once a day administration. However, Fujimoto during the test phase performs cyclooxygenase-2 dependent inhibitory activity after a single administration of the phenyl acetic acid compound by analyzing for the activity after 30 minutes to 8 hours of administration (page 8, lines 1-5). A once a day administration is assumed because the prior art administers 5-alkyl-2-arylaminophenylacetic acid is 5-methyl-2- (2'-chloro-6'-fluoroanilino) phenylacetic acid and specifically 5-methyl-2- (2'-chloro-6'-fluoroanilino) phenylacetic acid to treat cyclooxygenase-2 dependent disorders in mammals. Since the test was carried out within 30 minutes to 8 hours after a single administration, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Fujimoto to administer a dose of about 5-500 mg of 5-methyl-2- (2'-chloro-6'-fluoroanilino) phenylacetic acid with the expectation of detecting COX-2 inhibition. One having ordinary skill in the art would have been motivated to prepare the tablet or capsule formulation of Fujimoto and administer it once daily to a person in need thereof to treat cyclooxygenase-2 dependent disorders with the expectation that the blood/serum level of the drug administered once a day will be effective in maintaining the inhibitory effect.

In the remarks applicants while admitting that Fujimoto teaches a dose of about 5-500 mg active agent, state that in applicants invention about 200-1200 mg of active agent is

administered, which differs from the about 5-500 mg of active administered by Fujimoto. It may be pointed out that a point within the range of active agent of Fujimoto would coincide with a point within the instant claimed range. Secondly, applicants state that Fujimoto teaches a generic form of the 5-methyl-2- (2'-chloro-6'-fluoroanilino) phenylacetic acid. However, it is noted that applicants admitted on lines 1-3 of page 4 of applicants' disclosure that WO 99/11605 discloses 5-methyl-2- (2'-chloro-6'-fluoroanilino) phenylacetic acid. The study disclosed in instant Figure 4 is not compared to the drug formulation of Fujimoto. Thus, there is no demonstration in the Figure 4 that the instant drug formulation has unusual result over the drug formulation of Fujimoto.

Applicants also argue that claims 36-38 cannot be obvious over Fujimoto because Fujimoto does not disclose 5-methyl-2- (2'-chloro-6'-fluoroanilino) phenylacetic acid. However, it is noted that applicants admitted on lines 1-3 of page 4 of applicants' disclosure that WO 99/11605 discloses 5-methyl-2- (2'-chloro-6'-fluoroanilino) phenylacetic acid.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1, 2 and 4-41 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2 and 4-41 of prior U.S. Patent No. 09/950,538. In the remarks applicants admit that the instant claims are identical with the claims of application serial number 09/950,538. This is a double patenting rejection.

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600